

## REMARKS

Claims 1-12 and 14-15 are now pending.

The Applicants herein respectfully request the cancellation of claims 18 and 21 without prejudice. The Specification is amended at page 12 per the recommendation of the Examiner.

### Rejections under 35 USC § 102

The Applicants respectfully point out to the Examiner that processes for producing a composition of water-soluble phytomedicinal compounds, of the Applicants' invention, are drawn toward combining plant tissue with water, in a ratio of plant tissue to water within a range of about 1:5 to about 1:50, at a temperature between about 75°C and about 102°C for a period of time to solubilize a substantial portion of thermal aqueous extractable phytocompounds present in the plant tissue, to produce a first extract; and removing substantially all entities having a molecular weight greater than about 10 kd from the extract to produce a composition of water-soluble phytomedicinal compounds.<sup>1</sup> As a *physical corollary* compositions which necessarily result from disclosed processes of the present invention fully represent water soluble compounds between 0 and about 10,000 daltons. **However, in sharp contrast, compounds having a molecular weight between about 6000 and about 10,000 are necessarily absent in compositions resulting from the Ishihara, *et al.*, method.** Ishihara, *et al.*, specifically require "... concentrating the obtained extract by ultrafiltration membrane with a fractional molecular weight of 3000 to 6000 ...".<sup>2</sup> Accordingly, the Ishihara process is necessarily distinct; i.e., compounds having a molecular weight between about 6000 and about 10,000 are absent in the resulting Ishihara compositions.

The Applicants respectfully highlight the fact that, although the disclosures of both Ishihara, *et al.*, ('862 patent) and Lunder ('000 patent) are drawn toward plant extracts, including aqueous extracts, and related processes, *neither of these references* describes, contemplates, or suggests specifically removing substantially all entities having a molecular weight greater than

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<sup>1</sup> Applicants' written description, page 4, lines 21-28.

<sup>2</sup> Ishihara, *et al.*, ('862 patent) col.6, lines 18-19; col.7, lines 16-18; col.12, lines 58-59.

about 10,000 from the extract to produce a substantially complete composition of water-soluble phytomedicinal compounds less than about 10kd in size.

The Applicants accordingly respectfully request the Examiner to withdraw the rejections under 35 USC § 102.

### **Rejections under 35 USC § 103**

The Applicants respectfully highlight to the Examiner that large molecular weight entities that cause toxic side effects and/or function as inhibitor(s) of otherwise efficacious phytochemicals including metabolites are specifically removed to substantially eliminate all entities more than about 10,000 daltons in molecular weight. Particularly, resulting water-soluble compositions of the present invention are substantially devoid of molecular entities larger than about 10 kd.<sup>3</sup> The present invention particularly employs thermal aqueous extraction. Poor water-soluble portions are removed from the much more bioavailable water-soluble fraction. Moreover, the water insoluble ingredients are rich in highly aromatic compounds which are well-known to possess properties (e.g., oxidants, carcinogens) toxic to human physiology as are the excluded molecular entities greater than about 10 kd. Accordingly, processes of the invention described herein significantly enhance the efficacy and decrease the toxicity of medicinal plant extracts.<sup>4</sup>

Since none of the cited references describe, teach, contemplate, or suggest the production of plant extracts which have reduced toxicity and increased efficacy by means of thermal aqueous extraction and the removal of water-soluble molecular entities greater than about 10 kd to necessarily produce a composition of water-soluble phytomedicinal compounds between about 0 and about 10kd in size,<sup>5</sup> the Applicants respectfully submit that the claimed invention cannot be obvious as a matter of law.

The Applicants accordingly respectfully request the Examiner to withdraw the rejections under 35 USC § 103.

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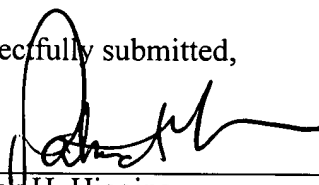
<sup>3</sup> Applicants' written description, page 3, lines 20-25.

<sup>4</sup> See, e.g., Applicants' written description, page 5, lines 15-21.

The Applicants respectfully submit that claims 1-12 and 14-15 are in condition for allowance. Early action toward this end is courteously solicited. The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution.

The Commissioner is further authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

Respectfully submitted,



Patrick H. Higgins  
Reg. No. 39,709  
Attorney for Applicant

DATE: June 2, 2005  
Fox Rothschild LLP  
997 Lenox Drive, Building 3  
Lawrenceville, NJ 08648-2311  
(609) 896-7654 (voice)

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<sup>5</sup> See, e.g., Applicants' written description, page 6, lines 29-31.